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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,134	07/11/2003	Gerold Schuler	106985-2 KGB	4429

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,134	SCHULER ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 11, 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 8/16/10, are acknowledged.
Claim 9 has been amended.
Claims 9, 11, and 29-30 are pending and are under examination.

2. In view of Applicant's amendment, the previous grounds of rejection are withdrawn. However, Applicant's arguments relevant to the new grounds of rejection will be addressed below.

3. The following are new grounds of rejection necessitated by Applicant's amendment.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11, and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites that the activation stimulus consists of at least one of: (a) plate-bound anti-CD3 and soluble anti-CD28; and (b) mature dendritic cells. The scope of the claim is unclear. Does the phrase "at least one of" refer to the elements recited in only (a), or do the claims encompass an activation stimulus consisting of a least one of the elements recited in (a) or (b)? For example, do the claims encompass an activation stimulus consisting of only anti-CD3, or do the claims require that one of anti-CD3 and anti-CD28 be combined with mature dendritic cells. Alternatively, the claims might be intended to require selecting an activation stimulus that consists of both anti-CD3 and anti-CD28 or an activation stimulus that consist of mature dendritic cells, or an activation stimulus that consists of a combination of anti-CD3/anti-CD28 and mature dendritic cells? For the purposes of applying prior art, the claims are being interpreted

such that the activation stimulus consist of at lease one the recited elements (i.e. anti-CD3, anti-CD28, or mature dendritic cells).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method comprising anergizing human CD4+CD25- T cells by contacting with CD4+CD25+ T cells and an activation stimulus, said activation stimulus consists of "at least one of" (a) plate-bound anti-CD3 and soluble anti-CD28 antibodies; and (b) "mature dendritic cells" (claim 29 and dependent claims 30-32).

Applicant indicates that support for the new limitations of the claims can be found at page 4 of the specification.

A review of the specification fails to reveal support for the new limitations.

The specification discloses that CD4+CD25+ T cells can be used to anergize CD4+CD25- T cells. The specification dislcoses that activation of CD4+CD25+ T cells is critical for anergy induction. The specification dislcoses examples wherein the CD4+CD25+ T cells are activated with plate-bound anti-CD3 and soluble anti-CD28, or with allogeneic mature dendritic cells. Applicant indicates that the specification on page 4 dislcoses the general use of dendritic cells for activation, which provides support for the instant claims. However, page 4 of the specification is directed to expanding Tr1-like regulatory T cells that have been obtained by anergizing CD4+CD25- T cells with

CD4+CD25+ T cells. This provides support for expanding Tr1 like regulatory T cells with mature dendritic cells. However, the specification does not disclose activating *CD4+CD25+ T cells* with any mature dendritic cell, as is encompassed by the instant claims. The specification only dislcoses activating CD4+CD25+ T cells with *allogeneic* mature dendritic cells, which has a narrower scope than the instant claims. Furthermore, the specification does not disclose using combinations of dendritic cells and anti-CD3/anti-CD28 antibodies, as is encompassed by the instant claims which are drawn to contact with "at least one of" anti-CD3/anti-CD28 or a mature dendritic cell.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dieckmann et al., June 2001 (of record).

Dieckman et al. teach a method comprising isolating CD4+CD25+ T cells from human peripheral blood and co-culturing said CD4+CD25+ T cells with total CD4+ T cells (i.e. a population comprising predominantly CD4+CD25- T cells) in the presence of an activation stimulus consisting of allogeneic mature dendritic cells or an activation stimulus consisting of plate-bound anti-CD3 and soluble anti-CD28 (see pages 1307-1308, in particular). Dieckman et al. teach that the allogeneic mature dendritic cells and the anti-CD3/anti-CD28 antibodies act as an activation stimulus for both the whole CD4 T cells (i.e. the CD4+CD25- T cells) and the CD4+CD25+ T cells. Thus, the method of Dieckman et al. results in the activation of CD4+CD25+ T cells with said activation stimulus, and contacting CD4+CD25- T cells with said activated CD4+CD25+ T cells and said activation stimulus, exactly as recited in the instant claims. Therefore, the method of Dieckman et al. would inherently result in the production of a Tr1 like regulatory T cells that produce IL-10 and suppress T cell proliferation since it is identical to the method of the instant claims.

Thus, the reference clearly anticipates the invention.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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